

REMARKS

This communication responds to the final Office Action mailed on April 8, 2008. Claims 1-9 and 18-29 are currently pending. Claims 1-3, 6-9, and 18-27 have been amended. Claims 28 and 29 have been withdrawn. In view of the following remarks, as well as the foregoing amendments, Applicants submit that this application is in complete condition for allowance in this regard.

Rejections of Claims Under 35 U.S.C. § 102

Claims 1-6, 8, 18-21, 23-25, and 27 over Brown

Claims 1-6, 8, 18-21, 23-25 and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 2,591,046 to Brown et al. (hereinafter *Brown*). The Examiner contends that *Brown* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Independent claim 1 sets forth “said axial grooves extending from approximately said first opening to approximately said tapered region.” In contrast, *Brown* discloses a syringe barrel (11) with grooves (25) that are localized over a small distance between the opposite ends of the syringe barrel (11). In particular and as apparent from FIGS. 1-4 of *Brown*, the grooves (25) are localized axially over a short length near the center of the barrel (11). The grooves (25) serve to permit the stored fluid (30) to bypass the piston (16) and mix with a dry medication (29), but only when the syringe is actually used by a force applied to plunger (21) so that the piston (16) is moved relative to the barrel (11) to the location of the grooves (25). Hence, the grooves (25) are intentionally located only near a central position so that, as the piston (16) is moved by force

applied to the plunger (21), the grooves (25) are eventually available to the stored fluid (30) as flow channels to permit the fluid (30) to flow past the piston (16) and mix with the dry medication (29). Otherwise, the grooves (25) would not block the flow of the stored fluid (30) past the piston (16) to reach the dry medication (29).

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because *Brown* fails to disclose “said axially-extending grooves extending from approximately said first opening to approximately said tapered region,” *Brown* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 2-6, 8, 18-21, 23-25, and 27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Brown*. Applicants note that the Examiner has failed to state a *prima case* of obviousness for dependent claims 2-6, 8, and 23-25. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 2-6, 8, and 23-25.

Claims 1-6, 8, 18-21, and 23-27 over Bachynsky

Claims 1-6, 8, 18-21, and 23-27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,971,953 to Bachynsky (hereinafter *Bachynsky*). The Examiner contends that

Bachynsky shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Independent claim 1 sets forth “said axial grooves extending from approximately said first opening to approximately said tapered region.”

In contrast, *Bachynsky* discloses a syringe barrel (11) with grooves (30) that are localized over a small distance between the openings at the opposite ends of the barrel (11). In particular, the grooves (5) are localized axially near the center of the barrel (11). The grooves (30) serve to permit the stored fluid (23) to bypass the piston (32) and mix with a dry medication (24), but only when the syringe is actually used by a force applied to plunger (40) so that the piston (32) is moved relative to the barrel (11) to the location of the grooves (30). Hence, the grooves (30) are intentionally located only near a central location relative to the ends of the barrel (11) so that, as the piston (32) is moved by the force applied to the plunger (40), the grooves (30) are eventually available to the stored fluid (23) as flow channels to permit the fluid (23) to flow past the piston (32) and mix with the dry medication (24). Otherwise, the grooves (30) would not block the flow of the stored fluid (23) past the piston (32) to reach the dry medication (24). Hence, the grooves (30) fail to extend from approximately the opening at the one end of the barrel (11) through which the piston (32) is inserted to approximately the tapered end of the barrel (11) that is near the needle (18).

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because *Bachynsky* fails to disclose “said axial grooves extending from

approximately said first opening to approximately said tapered region,” *Bachynsky* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 2-6, 8, 18-21, and 23-27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Bachynsky*. Applicants note that the Examiner has failed to state a *prima case* of obviousness for dependent claims 2-6, 8, and 23-25. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 2-6, 8, and 23-25.

Claims 1-6, 8, 18-25, and 27 over Grabenkort

Claims 1-6, 8, 18-25, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,779,668 to Grabenkort (hereinafter *Grabenkort*). The Examiner contends that *Grabenkort* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Independent claim 1 sets forth “said axial grooves extending from approximately said first opening to approximately said tapered region.”

In contrast, *Grabenkort* discloses a syringe barrel (11) with grooves (22) that are localized near only one of the opposite openings – open end (16). As apparent, the grooves (22) are widely separated from the opposite tapered region (12). The grooves (22) fail to extend from approximately the open end (16) to approximately the tapered region (12). In fact, the grooves (22) abruptly end a short axial distance along the barrel (11) from the open end (16). The

grooves (22) function to permit vapor resulting from thawing the frozen stored fluid (30) to escape the barrel (11) when the syringe is used. *See* col. 4, lines 58-61. Hence, the grooves (22) fail to extend from approximately the open end (16) of the barrel (11) to approximately the tapered end (12) of the barrel (11).

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because *Grabenkort* fails to disclose “said axial grooves extending from approximately said first opening to approximately said tapered region,” *Grabenkort* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 2-6, 8, 18-25, and 27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above. Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Grabenkort*. Applicants note that the Examiner has failed to state a *prima case* of obviousness for dependent claims 2-6, 8, and 23-25. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 2-6, 8, and 23-25.

Claims 1-8, 18-21, 23-25, and 27 over Reinhard

Claims 1-8, 18-21, 23-25, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,788,670 to Reinhard et al. (hereinafter *Reinhard*). The Examiner contends

that *Reinhard* shows or teaches all the elements of the rejected claims. Applicants respectfully disagree for the reasons set forth below.

Independent claim 1 sets forth “said axial grooves extending from approximately said first opening to approximately said tapered region.”

In contrast, *Reinhard* discloses a syringe barrel (1) with grooves (5) that are localized over a small distance between the openings at the opposite ends of the syringe barrel (1). In particular, the grooves (5) are localized axially near the center of the barrel (1). The grooves (5) function to permit the stored liquid in chamber (3a) to bypass the plunger (9) and mix with a dry component in chamber (2a), but only when the syringe is actually used by a force applied to plunger (9) so that the piston (8) is moved relative to the barrel (1) to the location of the grooves (5). *See* col. 6, lines 23-42. Hence, the grooves (5) are intentionally localized so that, as the piston (8) is moved by the force applied to the plunger (9), the grooves (5) are eventually available to the stored liquid as flow channels to permit the liquid in chamber (3a) to flow past the piston (8) and mix with the dry component in chamber (2a). Otherwise, the grooves (5) would not block the flow of the stored liquid past the piston (8) to reach the dry component in chamber (2a). Hence, the grooves (22) fail to extend from approximately the open end of the barrel (1) through which the piston (8) is inserted to approximately the tapered end (near the terminus of the lead line for reference numeral (4) of the barrel (1).

In order for a reference to anticipate the invention in a claim, the reference must teach each and every element in the precise arrangement set forth in the claim. If the reference fails to teach even one of the claimed elements, the reference does not and cannot anticipate the claimed invention. Because *Reinhard* fails to disclose “said axial grooves extending from approximately

said first opening to approximately said tapered region,” *Reinhard* fails to anticipate independent claim 1. Therefore, Applicants respectfully request that the Examiner withdraw the rejection.

Because claims 2-8, 18-21, 23-25, and 27 depend from independent claim 1, Applicants submit these claims are also patentable for at least the same reasons discussed above.

Furthermore, these claims recite unique combinations of elements not disclosed or suggested by *Reinhard*. Applicants note that the Examiner has failed to state a *prima case* of obviousness for dependent claims 2-6, 8, and 23-25. For this additional reason, Applicants request that the Examiner withdraw the rejection of claims 2-6, 8, and 23-25.

Rejection of Claims under 35 U.S.C. § 103(a)

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over *Brown*, *Bachynsky*, *Grabenkort*, or *Reinhard* in view of U.S. Patent No. 4,846,796 to Carrell et al. (hereinafter *Carrell*). Applicants submit that dependent claim 9 is patentable for at least the same reasons as independent claim 1. To establish a *prima facie* case of obviousness, the prior art references being combined must teach or suggest all the claim limitations. Furthermore, dependent claim 9 recites a unique combination of elements not disclosed or suggested by the combination of *Brown*, *Bachynsky*, *Grabenkort*, or *Reinhard* with *Carrell*.

Response to the Examiner’s Response to Arguments

The Examiner contends on page 6 of the Office Action “‘approximately’ is a relative term and is therefore very broad. Syringes are relatively small devices designed to be hand held and

therefore the examiner maintains that all the parts of a syringe can be considered to be approximately near another part of a syringe.” Applicants disagree with these contentions.

During examination of a patent application, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. The plain meaning of a claim term is the ordinary and customary meaning that the term would have to a person of ordinary skill in the art in question as of the effective filing date of the patent application.

According to its plain meaning, the term “approximate” in claim 1 is ordinarily and customarily defined as “close together but not exact.” *See* The American Heritage Dictionary, 3rd Ed. (Houghton Mifflin 1997). Despite the Examiner’s remarks to the contrary, the small size of a syringe is totally unrelated to the position of the grooves relative to the first opening and the position of the axial grooves relative to the tapered region. Claim 1 sets forth that the axial grooves extend from approximately (in other words, close to but not exactly at) the first opening in the barrel to approximately (in other words, close to but not exactly at) the tapered region of the barrel.

Words of approximation, such as “generally” and “substantially”, are descriptive terms commonly used in patent claims to avoid a strict numerical boundary to the specified parameter. Anchor Wall Systems v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1311 (Fed. Cir. 2003); Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1367 (Fed. Cir. 2001) (quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)); see, e.g., Andrew Corp v. Gabriel Elecs. Inc., 847 F.2d 819, 821-22 (Fed. Cir. 1988) (noting that terms such as “approach each other,” “close to,” “substantially equal,” and “closely approximate” are ubiquitously used in

patent claims and that such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts).

In claim 1, the use of the term “approximately” is used to avoid the strict numerical boundary that one end of each groove be located exactly at the first open end of the barrel and the opposite end of each groove be located exactly at the tapered region of the barrel. Hence, after the claim is properly construed, the issue for interpreting the disclosure in the prior references applied by the Examiner in the Office Action is not the absolute positions of the parts of a small syringe but, instead, the relative positions of the parts of a small syringe to determine whether or not these parts are approximate (close but not exactly at).

In *Brown*, the grooves (25) are localized over a small distance centrally between the opening at the one end of the barrel (11) into which the piston (16) is inserted and the tapered end of the barrel (11) that is near the needle (15). Hence, the grooves (25) fail to extend from approximately (close but not exactly at) the opening at the one end of the barrel (11) through which the piston (16) is inserted to approximately (close but not exactly at) the tapered end of the barrel (11) that is near the needle (15).

In *Bachynsky*, the grooves (5) are localized axially near the center of the barrel (11). Hence, the grooves (5) fail to extend from approximately (close but not exactly at) the opening at the one end of the barrel (11) through which the piston (32) is inserted to approximately (close but not exactly at) the tapered end of the barrel (11) that is near the needle (18).

In *Grabenkort*, the grooves (22) are localized near open end (16) through which the piston (34) is inserted. However, the grooves (22) terminate a rather short distance from the

open end (16). Hence, the grooves (22) fail to extend from approximately (close but not exactly at) the open end (16) of the barrel (11) to approximately (close but not exactly at) the tapered end (12) of the barrel (11).

In *Reinhard*, the grooves (5) are localized over a small distance centrally located between the unlabeled opening at the one end of the syringe barrel (1) through which the piston (8) is inserted and the tapered end (near the terminus of the lead line for reference numeral (4)) of the barrel (1). Hence, the grooves (22) fail to extend from approximately (close but not exactly at) the open end of the barrel (1) through which the piston (8) is inserted to approximately (close but not exactly at) the tapered end (near the terminus of the lead line for reference numeral (4)) of the barrel (1).

The Examiner states on page 6 of the Office Action that “the examiner maintains that the grooves are going to be greater than 5.1 microns even if the references do not disclose specific numbers.” Dependent claim 21 recites that “the surface roughness ranges from about 2.5 microns to about 5.1 microns.” Hence, Applicants submit that claim 21 is now patentable over *Brown*, *Bachynsky*, *Grabenkort*, and *Reinhard*.

In the Office Action, the Examiner asserts that each of the syringe structures in *Brown*, *Bachynsky*, *Grabenkort*, and *Reinhard* is capable of dispensing a fluid susceptible to void formation when the syringe and the fluid are frozen and then thawed and dismisses this language found in the preamble of independent claim 1 as “functional language”. Applicants note that none of these references discloses that the syringe structure is capable of dispensing this type of fluid. A person having ordinary skill in the art would not have recognized from the disclosure in any of these references that the syringe would be capable of dispensing such fluids.

Generally, Applicants' claim 1 is also non-obvious over *Brown*, *Bachynsky*, *Grabenkort*, and *Reinhard*, either alone or in combination, because they would not work for their intended purpose if the axial grooves were modified to extend from "approximately said first opening to approximately said tapered region." As explained above, none of the references applied by the Examiner teaches such axial grooves. In each instance, the absence of this teaching is a product of the disclosed use of the syringes. Specifically, the axial grooves in syringe of each reference represent bypass flow channels that permit components of a mixture to combine at the time that the mixture is injected into a patient. Otherwise, the components of the mixture are isolated from each other. Were the length of the grooves somehow extended in any of these references applied by the Examiner from "approximately said first opening to approximately said tapered region," as set forth in claim 1, then the components would never be isolated from each other and would readily mix. The primary objective of the syringe in each reference of isolating the components until the time of injection into a patient would be summarily defeated by such an attempted modification. In other words, the length of the grooves in the references applied by the Examiner could not be modified to be extended in length and still have an operative device that works for its intended purpose.

Conclusion

Applicants have made a bona fide effort to respond to each and every requirement set forth in the Office Action. In view of the foregoing remarks, this application is submitted to be in complete condition for allowance. Accordingly, a timely notice of allowance to this effect is

earnestly solicited. In the event that any issues remain outstanding, Applicants invite the Examiner to contact the undersigned to expedite issuance of this application.

Applicants do not believe any fees are due in connection with filing this communication. If, however, any petition or additional fees are necessary because of this communication, the Commissioner is hereby authorized to charge any under-payment or fees associated with this communication or credit any over-payment to Deposit Account No. 23-3000.

Respectfully submitted,
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